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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/728,707      | 12/04/2003  | Hiromitsu Takase     | 1232-5220           | 8604             |

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EXAMINER

CALAMITA, HEATHER

ART UNIT PAPER NUMBER

1637

DATE MAILED: 09/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |  |                               |  |
|------------------------------|--|-------------------------------|--|
| <b>Office Action Summary</b> | Application No.<br>10/728,707          | Applicant(s)<br>TAKASE ET AL. |  |
|                              | Examiner<br>Heather G. Calamita, Ph.D. | Art Unit<br>1637              |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 1-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-18, 20, 21 and 23 is/are rejected.
- 7) ☒ Claim(s) 19 and 22-28 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/27/2004</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/Restrictions*

1. Applicants' election with traverse of Group II (claims 13-28) in the reply filed on June 30, 2006, is acknowledged. The traversal is on the ground(s) that the technical features that define the contribution of applicants' invention are common to all of the pending claims. This is not found persuasive because the claims in Group I and the claims in Group II do not share a special technical feature as Addison et al. teach the method for analyzing a probe carrier. As this method is known in the art it therefore cannot have a special technical feature which constitutes applicants' contribution. The requirement is still deemed proper and is therefore made *FINAL*.

### *Status of Application, Amendments, and/or Claims*

2. Claims 1-28 are pending. Claims 13-28 are currently under examination. Claims 1-12 are withdrawn as being directed to non-elected subject matter.

### *Claim Rejections - 35 USC § 112*

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "and 10% or less" in claim 21 is a relative term which renders the claim indefinite. The term "and 10% or less" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. In claim 21 the recitation of 10% or less is undefined because it is not clear to what "and 10% or less" is in reference.

*Claim Rejections - 35 USC § 102*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13-18, 21, 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Addison et al. (Antiviral Research, 2000).

With regard to claim 13, Addison et al. teach a method for analyzing a probe carrier having a probe immobilized area in which a nucleic acid probe is immobilized and a phosphorus-containing area that contains phosphorus in a predetermined concentration on a carrier, comprising (see p. 34 Figure 3A and Figure 3 Legend, where the probe carrier is the membrane, the probe immobilized area contains the fragmented plasmid crosslinked to the membrane and the phosphorus containing area contains the fragmented plasmid with the P<sup>32</sup> labeled probes hybridized to the plasmid, where the pVg is the quantitation standard and is present in a known amount or predetermined amount):

a) detecting an amount of the phosphorus contained in the nucleic acid probe in the probe immobilized area as a first signal intensity (see Figure 3A and Figure 3 Legend, where the P<sup>32</sup> labeled probe hybridized to the cccDNA on the blot is the first signal intensity);

b) detecting an amount of the phosphorus in the phosphorus-containing area as a second signal intensity (see Figure 3A and Figure 3 Legend, where the P<sup>32</sup> labeled probe hybridized to the pVg quantitation standard on the blot is the second signal intensity); and

c) determining the nucleic acid probe in the probe immobilized area by standardizing the first signal intensity by using the predetermined concentration of the phosphorus in the

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phosphorus-containing area and the second signal intensity (see Figure 3A and Figure 3 Legend, where the intensity of the  $P^{32}$  labeled probe hybridized to the cccDNA and the intensity of the  $P^{32}$  labeled probe hybridized to the pVg quantitation standard on the blot is used to determine the cccDNA copy number).

With regard to claim 14, Addison et al. teach wherein the plurality of probes immobilized areas is each arranged independently on the carrier in a matrix form (see Figure 3A and Figure 3 Legend, where there are a plurality of probes distinctly arranged on the membrane in a matrix form).

With regard to claim 15, Addison et al. teach wherein the phosphorus-containing area is formed by implanting the phosphorus into at least a portion of the carrier [see Figure 3A and Figure 3 Legend, where the  $P^{32}$  labeled probe is hybridized to the fragmented plasmid DNA crosslinked to the membrane (i.e. the carrier)].

With regard to claim 16, Addison et al. teach wherein the phosphorus-containing area is formed as a film formed on at least a portion of a surface of the carrier (see Figure 3A and Figure 3 Legend, where the  $P^{32}$  labeled probe is hybridized to the fragmented plasmid DNA crosslinked to the membrane (i.e. the carrier) and the hybridization occurs in solution and the probe is considered as a "film").

With regard to claim 17, Addison et al. teach wherein a concentration of the phosphorus in the film is fixed in a depth direction (see Figure 3A and Figure 3 Legend, where the  $P^{32}$  labeled probe is hybridized to the fragmented plasmid DNA crosslinked to the membrane and the hybridized probe is fixed in a depth direction).

With regard to claim 18, Addison et al. teach wherein the phosphorus-containing area is formed by containing the phosphorus in an entire portion forming the surface having the probe immobilized area of the carrier (see Figure 3A and Figure 3 Legend, where the  $P^{32}$  labeled probe is hybridized in an entire portion to the fragmented plasmid DNA crosslinked to the membrane which forms the surface to which the probes (fragmented plasmid DNA) are immobilized).

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With regard to claim 21, Addison et al. teach wherein a content (weight ratio) of the phosphorus in the phosphorus-containing area is 0.1 ppm or more and 10 % or less [see Figure 3A and Figure 3 Legend, where the amount of phosphate in the P<sup>32</sup> labeled probe falls within 0-10% (10% or less is read as 0-10%) of all of the phosphorous in the phosphorous containing area on the membrane].

With regard to claim 23, Addison et al. teach the nucleic acid probe has a nucleic acid that is DNA (see Figure 3A and Figure 3 Legend, where the probe and the fragmented plasmid crosslinked to the membrane is DNA).

*Claim Rejections - 35 USC § 103*

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Addison et al. (Antiviral Research, 2000) in view of Lynch et al. (USPN 5,962,244, 1999).

The teachings of Addison et al. are described previously.

Addison et al. do not teach glass as a substrate.

Lynch et al. teach glass as a substrate (see col. 14 lines 50-57).

One of ordinary skill in the art at the time the invention was made would have been motivated to substitute glass as a support for the membrane as taught by Lynch because the substrates are known equivalents. It would have been prima facie obvious to substitute glass as a support for the membrane as taught by Lynch as this is a simple substitution of equivalents. One of skill in the art would be motivated

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to substitute glass as a support for the membrane as taught by Lynch since the glass substrate and the membrane are disclosed by Lynch as equivalents and therefore exchangeable (see col. 14 lines 50-57).

Furthermore, the motivation to make the substitution cited above arises from the expectation the prior art substrates will perform their expected functions to achieve their expected results when combined for their common known purpose.

*Allowable Subject Matter*

6. Claims 19, 22 and 23-28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

*Correspondence*

7 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Heather G. Calamita whose telephone number is 571.272.2876 and whose e-mail address is heather.calamita@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner can normally be reached on Monday through Thursday, 7:00 AM to 5:30 PM.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at 571.272.0782.

Papers related to this application may be faxed to Group 1637 via the PTO Fax Center using the fax number 571.273.8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to 571.272.0547.

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hgc

  
JEFFREY FREDMAN  
PRIMARY EXAMINER  
8/4/04